Tafas v. Dudas et al
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EXHIBIT 2

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CERTIFICATION ANALYSIS UNDER THE REGULATORY FLEXIBILITY ACT

Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications

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Abbreviations and Acronyms

AIPLA	American Intellectual Property Law Association
CFR	Code of Federal Regulations
ESD	Examination Support Document
FY	Fiscal Year
FR	Federal Register
NAICS	North American Industry Classification System
PALM	Patent Application Location and Monitoring
PCT	Patent Cooperation Treaty
RCE	Request for Continued Examination
SBA	Small Business Administration
SRR	Suggested Restriction Requirement
USC	United States Code
USPTO	United States Patent and Trademark Office

Executive Summary

The United States Patent and Trademark Office (USPTO) is revising the rules of practice in patent cases relating to continuing applications and requests for continued examination (together referred to as “continued examination filings”), and for the examination of claims in patent applications.

The final rule is intended to ensure that continued examination filings are used efficiently to move applications forward. In addition, the final rule requires applicants with a large number of claims to share the burden of examining the application by submitting an examination support document covering all of the claims in the application (whether in independent or dependent form). The USPTO expects that the changes to the rules of practice in this final rule will lead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of just what patentees claim and address the growing practice of filing (by a common applicant or assignee) of multiple applications containing patentably indistinct claims.

In response to comments addressing the proposed rules that were critical of the USPTO’s decision to certify the new rules as not having a significant economic impact on a substantial number of small entities, the USPTO has revised its certification analysis to more precisely estimate the final rule’s impact on small entities. In this report, the USPTO describes its revised methodology and the results of the certification analysis.

To evaluate significant impact, the study considers the ratio of Annualized Incremental Cost as a Percent of Revenue. Impacts are evaluated relative to two screening thresholds:

- Entities at or above a threshold value of three percent are presumed to face significant impacts unless additional analysis on these entities indicates this will not be the case.

- Entities at or above a threshold value of one percent are presumed to face more moderate impacts that qualify as significant if collectively incurred by a substantial number of small entities, as discussed below.

For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietor who currently is capable of paying for or financing all necessary patent application costs and maintenance fees (under current rules) associated with an application of a type that would be affected by the final rule. This study assumes that the minimum annual revenue that would support an individual’s living expenses, as well as his/her patent application and maintenance costs, is $75,000.

The analysis assumes that a “substantial number” of small entities exists if the number of entities impacted at a given impact threshold (e.g., three percent) constitutes more than 20 percent of all small entities that apply for patents.

This analysis estimates that the final rule will result in incremental costs that range from $872 to $13,993 per application (present value).[1] Based on the methodology and data described in this report, the resulting analysis indicates that no patent applicants will incur significant impacts (defined as annualized incremental costs in excess of three percent of revenue) due to the final rule. Although some applicants will exceed the lower screening threshold of one percent, the number of small entities in this category is estimated at only 54, or about 0.05 percent of all small entity applicants. Even using data for all applicants as a sensitivity analysis, only 157 small entity applicants fall into this category – about 0.04 percent of all applicants. These figures do not meet the criterion for a "substantial number" of small entities. Therefore, this analysis concludes that USPTO's final rule will not result in significant economic impacts on a substantial number of small entities.

[1] Current patent filing and maintenance costs for applicants that would be affected by the final rule are estimated at between $19,940 and $49,155.

1. Need for and Objectives of the Rule

The United States Patent and Trademark Office (USPTO) is revising the rules of practice in patent cases relating to continuing applications and requests for continued examination (together referred to as "continued examination filings"), and for the examination of claims in patent applications. This section of the report provides background information and briefly discusses the need for and objectives of the rule. Following some initial background information in Section 1.1 regarding how the patent application process currently works, and in Section 1.2 regarding USPTO's proposed rules and small entity certifications, Section 1.3 briefly describes the final rule revisions and the objectives they are designed to meet. These changes will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

1.1 Background

To provide context for understanding the need for and objectives of the final rule, this section presents an overview of the current patent application review process. When an inventor wants to establish ownership of an invention by patenting it, s/he prepares and submits a patent application to the USPTO. One of the key elements of a patent application is the statement of "claims." In the context of a patent or patent application, claims provide the legal description that bounds whatever the inventor is claiming as his or her invention. There are two types of claims: independent and dependent. An independent claim stands by itself as a description of the invention or an aspect of the invention. Dependent claims, in the simplest of terms, reference an independent claim and cannot stand on their own. In some cases, dependent claims may describe ancillary features, (e.g., "bells and whistles") related to the more fundamental independent claims. In FY 2006, the number of independent claims in patent applications under review by the USPTO ranged from 1 to over 50, and the number of total claims ranged from 1 to over 350. According to USPTO staff, a typical patent application has 20 total claims, while an average patent application has approximately 21 total claims, including approximately 3 independent claims.

According to USPTO staff estimates, over 90 percent of patent applicants use a patent attorney to prepare and prosecute their patent applications. A typical patent application contains many elements, including specifications, claims, and drawings. Most applicants (55 percent) conduct a patent search and include a description of it in the application, although this is not a requirement and many applicants (45 percent) do not conduct a patent search.

The Application Process

Once an applicant submits his or her patent application, a USPTO patent examiner examines the application. Following the initial examination, the USPTO will take an "initial first action" on the application. If the patent examiner's initial first action is a rejection, then the applicant may file a response to the USPTO's initial first action. In general, the applicant's response will modify the application in some respect, including by deleting claims (usually) or adding claims (occasionally). Following this response, the patent examiner will issue his or her final action on the patent application.

If the USPTO does not grant the patent in the final action, the patent applicant may pursue further prosecution of the rejected application. The process that the applicant pursues varies by case, and there is not a "typical" prosecution path through the patent approval system. However, for the purposes of this final rule, this analysis describes one of the application prosecution paths that would trigger the final rule's continued examination filing requirements, which are described in Section 1.3.

Following the USPTO's final action, an applicant may decide to file a continuation application. A continuation is considered a separate application relative to the initial application. However, everything that the inventor claims in the original application is once again claimed in the continuation application, and it should not include any new matter. (If the applicant wishes to add new subject matter, the applicant would instead file a continuation-in-part.) Similar to the initial application, the USPTO takes a first action on the continuation and the applicant will be able to respond to that first action if necessary by deleting or adding claims or making other modifications. Following the applicant's response, the USPTO issues its final action on the first continuation.

If the final action on the continuation is a rejection, the applicant may continue prosecution of his or her application by filing a second continuation application. As described for the first continuation, the USPTO issues a first action, and the patent applicant may submit a response to the first action on the second continuation. Following the applicant's response, the USPTO issues its final action on the second continuation.

The patent applicant may then decide to file a "request for continued examination" (or "RCE"). An RCE is not a separate application; instead it is a request for continued examination of an application (initial, continuation, or continuation-in-part), without requiring the applicant to file a continuing application. Although an RCE is not considered an application, the USPTO responds with a first action, and the applicant may respond to the first action. After this response, the USPTO issues its final action on the RCE.

If the final action on the RCE is a rejection, the applicant may continue prosecution of his or her application by filing a third continuation application, and so on. The baseline (i.e., current) application cost estimated in this study assumes that the USPTO grants the patent after the third continuation and after the applicant pays the USPTO's issue fee.[2]

Over the 20-year lifespan of the patent, the USPTO requires patent holders to pay three patent maintenance fees. These fees are due 3 ½, 7 ½, and 11 ½ years from the date of the original patent grant.

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[2] Applicants that are issued patents earlier in the process would incur lower costs but would not be affected by the final rule's requirements for continued examination filings.

Patentably Indistinct Claims

USPTO's current rules of practice provide that "Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application." (See current Sec. 1.78(b).) Despite this existing rule, the USPTO still receives multiple applications with overlapping disclosures, a common inventor, and the same filing date.

Patent law prevents an inventor from obtaining two patents that cover the same invention or an obvious variation of the same invention. In cases where the patents cover identical inventions, the second patent is considered invalid. If there are obvious variations between the patents, the applicant may file a terminal disclaimer that states that the second patent to issue will expire on the same date as the first patent. This terminal disclaimer eliminates the possibility of an inventor gaining an improper extension of the patent period resulting from the second patent. To prevent double patenting, the patent examiners must closely inspect these applications and require applicants to either file a terminal disclaimer or combine applications that should have been filed as one application.

Need for the Rule

Although the filings affected by this rulemaking (including continued examination filings, applications with large numbers of claims, and applications with indistinct claims) are relatively few in number, they occupy a disproportionate portion of USPTO resources. Therefore, the USPTO spends a disproportional amount of its review time on relatively few applications, which takes away from the review time that the USPTO could otherwise commit to new initial applications. This situation is a significant cause of the backlog of unexamined applications before the USPTO and has created the need for the rule.

1.2 The Proposed Rule and Certification

The USPTO published two proposed rules in January 2006 (Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, *71 Federal Register 48*, January 3, 2006); and Changes to Practice for the Examination of Claims in Patent Applications, *71 Federal Register 61*, January 3, 2006). Under the first proposed rule, which addressed continuing applications, RCEs, and patentably indistinct claims, the USPTO proposed to change the rules of practice to require that: (1) any second or subsequent continued examination filing (continuation or continuation-in-part application or request for continued examination) include a showing as to why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution after a single continuation or continuation-in-part application or request for continued examination; and (2) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications.

Under the second proposed rule, which addressed the examination of claims, the USPTO proposed to revise application review practices as follows: (1) the USPTO would conduct an initial examination only of "representative claims," which would have included all of the independent claims and only the dependent claims that the applicant expressly designated for initial examination; and (2) if the number of representative claims is greater than ten, the USPTO would require the applicant to share the burden of examining the application by submitting an examination support document (ESD) to provide certain information regarding all of the representative claims.

In each of the two published notices, the USPTO certified that an initial Regulatory Flexibility Act analysis was not required because the proposed changes would not have a significant economic impact on a substantial number of small entities. In response to this certification, the USPTO received a number of comments, which are discussed in Section 2.

1.3 Summary of the Final Rule

The final rule combines the two proposed rules described above. As a convenience, this analysis distinguishes between the final rule requirements that originated in the first proposed rulemaking (the "continued examination filing requirements") and the final rule requirements that originated in the second proposed rulemaking (the "claims requirements") because many applicants are not affected by both sets of requirements.

Continued Examination Filing Requirements

The USPTO is changing the continued examination practice because each continued examination filing, whether a continuing application or request for continued examination, requires the USPTO to delay taking up a new application and thus contributes to the backlog of unexamined applications before the USPTO. Further, the current practice allows an applicant to generate an unlimited string of continued examination filings from an initial application. In such a string of continued examination filings, the exchange between examiners and applicants becomes less beneficial and suffers from diminishing returns with each continued examination filing.[3]

Therefore, in the final rule, the USPTO revised the continued examination filing rules so that an applicant may file at most two continuing applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application) plus a request for continued examination in any one of the initial application or two continuation or continuation-in-part applications, without any showing (referred to as a "petition" in this analysis) as to why the amendment, argument, or evidence could

[3] See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Federal Register 48,* January 3, 2006.

not have been submitted prior to the close of prosecution after a single continuation or continuation-in-part application or request for continued examination. Any additional continuation application, continuation-in-part application, or request for continued examination, however, would have to be supported by a petition in order to be considered by the USPTO.

The final rule also eases the burden of examining multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common assignee by requiring that all patentably indistinct claims in such applications be submitted in a single application (absent good and sufficient reason).[4]

The current, unrestricted continued examination practice and the filing of multiple applications containing patentably indistinct claims are impairing the USPTO's ability to examine new applications, even without real certainty that these unrestricted practices effectively advance prosecution, improve patent quality, or serve the typical applicant or the public. The final rule is intended to ensure that continued examination filings are used efficiently to move applications forward. The USPTO expects that the changes to the rules of practice in this final rule will: (1) lead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of just what patentees claim; and (2) address the growing practice of filing (by a common applicant or assignee) of multiple applications containing patentably indistinct claims.

Claims Requirements

In response to the proposed claims rule, the USPTO received a substantial number of comments from the public opposing the "representative claims" examination approach and suggesting that the USPTO simply adopt a strategy based upon whether an application contains more than a given number of independent and total claims. In response to these public comments, the USPTO modified the final rule to make the presentation of more than five independent claims or more than twenty-five total claims (rather than the presentation of more than ten representative claims) the threshold for invoking the examination support document requirement.

The final rule provides that if the number of independent claims is greater than five, or the number of total claims is greater than twenty-five, the applicant must share the burden of examining the application by submitting an examination support document covering all of the claims in the application (whether in independent or dependent form).

The final rule will not require small entities, as defined in 13 CFR 121.802, to include in their ESDs one of the elements that would have been required under the proposed rule. Small entities will not need to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. Large entities, however, will need to include this information in their ESDs.

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[4] The analysis estimates that there will be no incremental costs resulting from this requirement, as discussed in Section 4.

2. Significant Issues Raised by Public Comments

In response to the proposed rulemakings, the USPTO received 342 comments on the continuing application requirements, and 198 comments on the claims requirements. This section summarizes only the comments addressing the USPTO's certification of the proposed rules under the Regulatory Flexibility Act.

A number of comments generally asserted that the USPTO did not comply with the requirements of the Regulatory Flexibility Act in certifying that the changes in the proposed rulemakings will not have a significant economic impact on a substantial number of small entities. The comments stated that:

(1) the definition of small entities used by the USPTO in its certification of the proposed rules is designed for the purpose of paying reduced patent fees and excludes any application from a small business that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status;

(2) the USPTO's certification did not adequately address the impact of the proposed rules on small entities, and the USPTO failed to provide a credible factual basis to justify its certification that the proposed rules would not have a significant economic impact on a substantial number of small entities in compliance with 5 U.S.C. 605(b);

(3) the rule changes would have a significant economic impact on a substantial number of small entities seeking patents due to the additional costs associated with preparing an application, establishing the required showing under proposed § 1.78(d)(1)(iv) and § 1.114(f), and supplying an examination support document in compliance with proposed § 1.261, and would hinder the abilities of small entities to enhance their applications and protect their inventions;

(4) the USPTO should prepare an initial Regulatory Flexibility Analysis and republish the proposed rules before issuing any final rule to enable the USPTO to closely examine the impact on the affected small entities, encourage small entities to comment on additional information provided by the analysis, identify viable regulatory alternatives to the proposed rules, and demonstrate the USPTO's compliance with the Regulatory Flexibility Act;

(5) the USPTO did not describe any viable alternatives to the proposed rules to provide regulatory relief to small entities as required under 5 U.S.C. 603(c);

(6) the rule changes would be invalid and vulnerable to challenges under 5 U.S.C. 611 if the USPTO fails to comply with the requirements of the Regulatory Flexibility Act;

(7) the USPTO should exempt small entities from complying with the proposed rules to avoid further scrutiny under the Regulatory Flexibility Act; and

(8) in light of the fact that several large companies support the proposed changes it is questionable whether the rule changes are truly neutral towards small companies and that a bias in favor of large companies and against small entities could be in violation of the Regulatory Flexibility Act.

In response to the comments that were critical of the USPTO's decision to certify, the USPTO has established a business size standard for purposes of conducting analyses or making certifications under the Regulatory Flexibility Act for patent-related regulations (see *71 Federal Register 67109*, November 20, 2006). The USPTO also has revised its certification analysis to more precisely estimate the final rule's impact on small business entities. In this report, the USPTO describes its revised methodology and results of the certification analysis.

In addition, in response to public comments on the proposed rules, including those comments described above, the USPTO revised the continued examination filing requirements in the final rule. Under the proposed rule, the USPTO would have required applicants to file a petition with the second continuation, continuation-in-part, or RCE. The final rule allows two continuations and an RCE without a petition. This relaxation in rule language will reduce the number of affected small entities.

In addition, the USPTO changed the final rule requirements to exempt small businesses, as defined in 13 CFR 121.802, from one of the requirements in the ESD. Under the final rule, the USPTO will not require these small entities to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. The USPTO considers this element of the ESD to be the most challenging for patent applicants. As a result, the costs associated with the final rule will be reduced considerably for small entities.

3. Description and Estimate of the Number of Affected Small Entities

To identify the small entities affected by the final rule, this analysis first considers, in Section 3.1, the industries affected by the rule. Section 3.2 then focuses on the definition of small entity that this analysis uses and also estimates the number of small entities affected by the final rule.

3.1 Industries Affected by the Rule

Patents are intended to spur research and innovation. Because research and innovation can occur in any industry, the universe of potential patent applicants includes all industries. Certain industries tend to account for relatively larger shares of patent filings over certain time periods, but the industries that comprise this group can shift over time. Moreover, the span of industrial fields that generate patent filings is quite broad, as suggested by the USPTO's organization of some of its patent filing review activities around the following seven broad "technology centers":

- Biotechnology and Organic fields
- Chemical and Materials Engineering fields
- Computer Architecture Software and Information Security
- Communications
- Semiconductors, Electrical and Optical Systems and Components
- Transportation, Electronic Commerce, Construction, Agriculture, Licensing and Review
- Mechanical Engineering, Manufacturing and Products

The USPTO does not collect or maintain statistical data on how many patents or patent filings fall within a given industry. This analysis assumes that patent applicants are spread across all industries and that all industries will be equally impacted by the rule.[5]

3.2 Small Entities

3.2.1 Definition of "Small Entity"

The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code.

The USPTO, however, recently adopted an alternate size standard as the size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations (see 71 *Federal Register* 67109, November 20, 2006 for a detailed discussion of the USPTO's considerations in establishing this size standard).[6] Unlike the SBA small business size standards set forth in 13 CFR 121.201, this size standard is not industry-specific. Specifically, the USPTO's definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) meets the SBA's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition.

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[5] Although some industries may generate relatively more patent applications than others (as noted above), these industries are not more likely to face significant impacts because the applications are most likely to come either from large entities or from small entities that are able to attract investment capital. The analysis described in this report is not sensitive to this assumption.

[6] This small business size standard previously was established for purposes of identifying the criteria entities must meet to pay reduced patent fees; patent applicants that choose to self-identify themselves on the patent application qualify for reduced patent fees. The USPTO captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to USPTO. Some patent applicants contend that applicants do not always self-identify as small entities even though they would qualify for reduced fees by doing so. Assuming this is true, then data from PALM would understate the number of small entity applicants. The analysis specifically considers this possibility, as detailed in Section 3.2.2.

3.2.2 Small Entities Affected by the Rule

This analysis estimates the number of small entities using two alternative sets of data taken from the USPTO's Patent Application Location and Monitoring (PALM)[7] database system, which tracks information on each patent application submitted to USPTO:

(1) Small Entity Data Set. The first data set consists of data for just those FY 2006 filings for which the applicant self-identified as a small entity for purposes of paying reduced patent fees. Some patent applicants, however, contend that applicants do not always self-identify as small entities even though they would qualify for reduced fees by doing so. To the extent that this is true, then this first data set will understate the number of small entity applicants.

(2) All Entity Data Set. As a sensitivity analysis, the second data set considers data for all FY 2006 filings. The rationale for this data set is drawn from a report issued by the Small Business Administration stating that approximately 99.9 percent of businesses qualify as small entities using a size threshold of 500 employees (i.e., the same threshold that appears in the USPTO alternative definition of small entity).[8] Therefore, the second data set considers data for all FY 2006 filings as an approximation of the 99.9 percent figure. This data set clearly is overly conservative (it implicitly assumes that large entities do not submit any patent filings) and is useful primarily as a bounding case.

Regardless of which data set is used, however, not all entities will be affected by the final rule or will incur impacts. Therefore, this study analyzes each data set to estimate the number of small entities affected by the final rule. Affected small entities fall into one of three categories: (1) filings affected by the claims requirements only; (2) filings affected by the continued examination filing requirements only; and (3) filings affected by both the claims and the continued examination filing requirements.

[7] The number of applications included in this analysis account for only those applications with claims data reported in PALM. The USPTO receives some applications without knowing the number of claims in the application. As a result, the number of applications the USPTO received in FY 2006 may be higher than what is reported in this report.
[8] Small Business Administration Office of Advocacy. *The Small Business Economy For Data Year 2005, A Report to the President.* U.S. Government Printing Office: Washington, DC. December 2006. See page 8.

Note: It would be preferable to use data for each applicant, rather than each filing, in order to evaluate impacts on any applicants that submit more than one patent filing. The data obtained from PALM do not support such an analysis. Consequently, this analysis inherently assumes that each applicant submits patent filings pertaining to one invention within any given year. There is some support for this assumption, at least for smaller applicants, based on comments requesting that applicants continue to be permitted to file divisional applications serially (i.e., as through continuations or continuation-in-parts), rather than in parallel (i.e., by submitting multiple related applications simultaneously), in order to spread out the associated cost burden over time. This assumption likely does not hold for many large firms and it may not hold for some small firms. Nevertheless, it is likely to hold for most of the very smallest entities (e.g., sole proprietorships) that can least afford an incremental burden.

Entities Affected by the Claims Requirements

The claims requirements in the final rule apply to a portion of total initial patent applications filed. In fiscal year 2006, there were 285,324 initial applications. The final rule requirements apply to patent applications with more than five independent claims or more than 25 total claims. However, as described in the *Federal Register* notice accompanying the final rule, USPTO staff believe that once the final rule is adopted, applicants with more than five but less than 15 independent claims, or more than 25 but less than 75 total claims, will choose to prosecute their application in a manner that does not trigger the claims requirements. They will be able to do this under the final rule by submitting an initial application containing up to five independent claims and up to 25 total claims, and then adding a similar number of claims in each of two continuation applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application) as permitted without a petition (see Section 1).

As a result, this analysis anticipates that the claims requirements, if they had been applied to applications during FY 2006, would have affected only those initial patent applications having more than 15 independent claims or more than 75 total claims. Based on analysis of PALM data on total claims in initial patent applications,[9] approximately 1,105 filings, or 1.0 percent, submitted by small entities and 3,742 filings, or 0.9 percent, submitted by all entities in FY 2006 would incur costs under the claims requirements. These affected applications can be further subdivided, however, into two groups.

- Claims Requirements Only. 780 of the small entity initial applications (1.0 percent) affected by the claims requirements, or 2,818 of all initial applications (1.0 percent), have 15 or more independent claims and 75 or more total claims. These initial applications are not affected by the continued examination filing requirements.

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[9] PALM contains data on the number of independent claims and total claims in each application. Based on analysis of this data, a "rule-of-thumb" approximation is one independent claim out of every seven total claims. Assuming this distribution, the typical application will exceed the threshold for total claims more frequently than the threshold for independent claims. The analysis models total claims based on reported independent claims and the rule-of-thumb described above.

- Continued Examination Filing Requirements and Claims Requirements. 325 of the small entity filings (0.3 percent) affected by the claims requirements, or 924 of all filings (0.2 percent), are also are affected by the continued examination filing requirements.

Entities Affected by the Continued Examination Filing Requirements Only

The final rule requirements related to continued examination filings apply to applications or chains of continued examination filings that include more than two continuing applications (continuation or continuation-in-part applications), and more than a single request for continued examination in any one of these three applications (the initial or two continuing applications). Note that these are not the same as initial applications, as discussed in Section 1. For example, while there were 285,324 initial applications in FY 2006, there were 408,396 total filings. A portion of these total filings would be affected by the final rule's continued examination filing requirements.

To estimate the affected entities, this analysis assumes that all applicants filing their third, fourth, fifth, or greater continuing application and continuation-in-part application will be affected by the continued examination filing requirements. Exhibit 3-1 shows a box

Exhibit 3-1
Applications Affected by the Continued Examination Filing Requirements, Out of all Applications

APPLICATION PROSECUTION STAGE	**NUMBER OF INDEPENDENT CLAIMS/ TOTAL CLAIMS IN THE APPLICATION**	
Initial Application	< 15 IC / < 75 TC	> 15 IC / > 75 TC
First CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Second CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Third CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Fourth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Fifth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Sixth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Seventh CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Eighth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Ninth CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC
Tenth+ CON/CIP	< 15 IC / < 75 TC	> 15 IC / > 75 TC

around the affected applications. The double-lined box surrounds applications affected by the continued examination filing requirements. Those applications in the center column are affected only by these requirements, whereas those in the right column also are affected by the claims requirements.[10]

In addition to the applications identified in Exhibit 3-1, this analysis also considers FY 2006 RCE filings to determine those RCE filings that trigger the continued examination filing requirements under the final rule.

Based on analysis of PALM data, approximately 3,300 filings, or 3.0 percent, submitted by small entities and 11,326 filings, or 2.8 percent, submitted by all entities in FY 2006 would incur costs under the continued examination filing requirements. These affected filings can be further subdivided, however, into two groups.

- Continued Examination Filing Requirements Only. 2,995 of the small entity filings (2.7 percent) affected by the continued examination filing requirements, or 10,402 of all filings (2.6 percent), have 15 or fewer independent claims and 75 or fewer total claims. These filings are not affected by the claims requirements.

- Continued Examination Filing Requirements and Claims Requirements. 325 of the small entity filings (0.3 percent) affected by the continued examination filing requirements, or 924 of all filings (0.2 percent), have more than 15 independent claims or more than 75 total claims. These filings also are affected by the claims requirements.

Summary of Small Entities Affected by the Final Rule

Exhibit 3-2 summarizes the results described above.

Exhibit 3-2
Summary of Affected Small Entities

	Small Entity Data Set			All Entity Data Set		
	Total in Universe	Number Affected	Percent Affected	Total in Universe	Number Affected	Percent Affected
Only Claims Requirements	79,050	780	1.0%	285,324	2,818	1.0%
Only Continued Examination Filing Requirements	111,178	2,995	2.7%	408,396	10,402	2.5%
Both	111,178	325	0.3%	408,396	924	0.2%

[10] The methodology used to quantify the applications represented in the exhibit results in significant double-counting of claims. As a result, the analysis will overstate the number of applications affected simultaneously by both the claims requirements and the continued examination filing requirements.

4. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The final rule establishes three compliance requirements that will allow the USPTO to conduct a better and more thorough and reliable examination of patent applications.

- Submittal of an examination support document (ESD) for certain applications;
- Submittal of a petition in support of certain requests for continuing applications or continued examinations;
- Submittal of information related to patentably indistinct claims.

The following subsections discuss these requirements and estimate the associated burden on applicants that must comply with them.

To develop the estimates for the incremental costs resulting from the requirements of the final rule, the analysis uses the following information and data sources:

- Activities resulting in costs were identified based on a review of the draft final rule (provided by the USPTO), the proposed rules, and on discussions with USPTO staff.[11]

- USPTO fees charged of patent applicants and patent holders were taken from the USPTO's fee schedule.[12]

- The costs associated with baseline patent application preparation were taken from an American Intellectual Property Law Association (AIPLA) report entitled *Report of the Economic Survey 2005*.[13]

- Finally, USPTO staff provided estimated unit costs for a variety of factors, as noted in Appendix A.

All costs are calculated in 2006 dollars. The analysis applies a legal services labor rate of $233 per hour[14] (a composite of attorney and paralegal wage rates), and conservatively assume the applicant's labor rate is $150 per hour. The resulting costs are summarized in Section 5.2.

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[11] *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 *FR* 48 (Jan. 3, 2006) ; *Changes to Practice for the Examination of Claims in Patent Applications*, 71 *FR* 61 (Jan. 3, 2006)

[12] http://www.uspto.gov/web/offices/ac/qs/ope/fee2007february01.htm.

[13] AIPLA. *Report of the Economic Survey 2005*. Arlington, VA. September 2005.

[14] This labor rate is a blended composite wage based on data from the AIPLA report entitled *Report of the Economic Survey 2005*. The analysis updated the 2004 composite wage rate to 2006 dollars based on the Consumer Price Index.

4.1 Examination Support Document

Under the final rule, patent applicants will be required to submit an ESD if the application contains more than five independent claims or more than 25 total claims. The final rule states that the ESD must contain the following six elements (Section 1.261(a)(1)-(6) of the final rule):

(1) A statement that a preexamination search was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;
(2) An information disclosure statement in compliance with § 1.98 citing the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form);
(3) For each reference cited, an identification of all the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference;
(4) A detailed explanation of how each of the claims (whether in independent or dependent form) is patentable over the references cited with the particularity required by § 1.111(b) and (c);
(5) A concise statement of the utility of the invention as defined in each of the independent claims; and
(6) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such application in which such support exists.

Patent applicants with applications that exceed the independent or total claims thresholds will incur costs to prepare and submit the ESD.

To estimate the cost of the ESD, the analysis considers each of the six elements in the ESD.

The first element of the ESD requires the applicant to conduct a patent search. Although applicants currently are not required to conduct a patent search, most patent applicants (55 percent) conduct one as part of the application process. According to AIPLA estimates, the cost of a patent search ranges from approximately $1,000 for a relatively simple patent application up to approximately $2,500 for a relatively complex patent application.

Under the final rule, applicants that must prepare an ESD will have an incentive to complete the patent search prior to completion of their applications and ESDs. The reason for this is that doing so will reduce their costs for completing other portions of the

ESD (due to the heightened familiarity they will have with the patent search relative to the application). Given this incentive, it would be reasonable to assume that all applicants required to prepare an ESD (including conducting a patent search) would choose to complete the patent search prior to completing their application. Such an assumption would allow the analysis to account for lower ESD preparation costs than apply in cases where the patent search is not conducted until after the application is completed. Nevertheless, as a conservatism, the analysis assumes that only 50 percent of applicants in this situation will conduct the patent search prior to completing the application. The remaining 50 percent of applicants facing ESD requirements are assumed to complete the application first, even though doing so leads to higher ESD preparation costs.

Exhibit 4-1 presents the time estimates for each element of the ESD, assuming the applicant has/hasn't completed the patent search prior to completing the application.

Exhibit 4-1
Examination Support Document Time/Cost Estimates

ESD Element	Cost Basis	Estimate Assuming Patent Search is Conducted Prior to Application	Estimate Assuming Patent Search is Conducted After Application
Element 1	Application-based	$1,000 - $2,500	$1,000 - $2,500
Element 2	Application-based	1 hour	1 hour
Element 3*	First two independent claims	30 minutes each	40 minutes each
	Remaining independent claims	10 minutes each	10 minutes each
	First 10 dependent claims	10 minutes each	10 minutes each
	Remaining dependent claims	5 minutes each	5 minutes each
Element 4	Independent claims	10 minutes each	15 minutes each
	Dependent claims	No additional time needed	No additional time needed
Element 5	Application-based	30 minutes	30 minutes
Element 6	First two independent claims	20 minutes each	20 minutes each
	Remaining independent claims	10 minutes each	10 minutes each
	Dependent claims	5 minutes each	5 minutes each

* To mitigate the final rule's cost impact on small entities, the USPTO will not require small entities, as defined in 13 CFR 121.802, to complete Element 3 of the ESD.

This analysis assumes that the cost associated with three of the ESD elements is "application-based." Specifically, for elements 1, 2, and 5 of the ESD, applicants will incur a flat cost. Conversely, the cost incurred by applicants to complete elements 3, 4, and 6 of the ESD will vary depending on the number of independent and dependent claims in an application. To reduce the final rule's cost impact on small entities, however, the final rule does not require small entities to complete Element 3.

Exhibit 4-2 summarizes the resulting estimates of incremental ESD costs for affected small entities.

- Assuming a patent search is conducted before the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from $2,563 to $10,136.

- Assuming a patent search is conducted after the patent application is completed, this analysis estimates that the incremental cost associated with the ESD ranges from $5,170 to $13,121.

Exhibit 4-2
Summary of Small Entity Incremental Costs Associated with the ESD

	Incremental Cost
For applicants that already conduct a patent search in the baseline	$2,563-$10,136*
For applicants that do not conduct a patent search in the baseline	$5,170-$13,121*

* Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

4.2 Petition for Continuing Applications or Continued Examinations

The final rule also sets a reporting requirement related to continued examination filings. According to the final rule, an application or chain of continued examination filings may include no more than two continuing applications (continuation or continuation-in-part applications), and no more than a single request for continued examination in any one of these three applications (the initial or two continuing applications), without a petition showing why the amendment, argument, or evidence presented could not have been previously submitted. Based on a USPTO staff estimate, this analysis estimates that the petition required under the final rule will cost applicants $1,000 to complete.[15]

[15] In the OMB Paperwork Burden Analysis for the proposed continued examination filings rule, the USPTO estimated the cost of the petition to be $572. As a conservatism, this analysis assumes the cost of the petition will be higher ($1,000).

4.3 Information Related to Patentably Indistinct Claims

The final rule also contains a reporting requirement to address patentably indistinct claims. This requirement applies to applicants with pending applications or patents that (1) have an effective filing date within two months of the filing date of the pending application; and (2) name at least one inventor in common with the pending application. Under the final rule, the applicant must name these other commonly-owned applications or patents and must file a terminal disclaimer or explain how the applications (or application and patent) contain only patentably distinct claims if they have the same effective filing date and contain substantial overlapping disclosure.

The analysis estimates that there will be no costs associated with the indistinct claims portion of the rule. The intention of the provision is to close a loophole that might otherwise open after the ESD provisions are promulgated. That is, to avoid preparing an ESD, an applicant might otherwise be able to divide his or her claims among two simultaneous applications ("parallel prosecution"). The indistinct claims provision would prevent this by forcing applicants to justify the indistinct claims in the applications, submit a terminal disclaimer (the costs of which are associated with existing rules) or, more likely, abandoning one of the applications and adding its claims to the other application. USPTO staff believe it would not be possible to successfully justify the dual applications in this case. The applicant, too, would realize this and therefore would not submit such applications. Thus, given that the final rule would establish these rules in advance, the effect of the indistinct claims provision would be to prevent the dual application scenario from being used as a means of avoiding the ESD requirement.

Applicants currently file dual applications for reasons other than avoiding the prospective ESD requirement. This final rule would not generate incremental costs in this situation because 37 CFR 1.78(b) currently provides that applicants can be required to eliminate patentably indistinct claims from all but one application and the double patenting doctrine requires a terminal disclaimer if the patentably indistinct claims are not eliminated from all but one application.

5. Impacts Assessment

To comply with the Regulatory Flexibility Act, agencies must determine whether proposed actions will have a significant economic impact on a substantial number of small entities. If the action will not have a significant impact on a substantial number of small entities, then the agency may certify that this is the case instead of preparing a regulatory flexibility analysis, as would otherwise be required under the Act.

This section considers whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities. Section 5.1 describes the methodology used in this assessment. Section 5.2 presents the results of the analysis. Finally, Section 5.3 draws conclusions regarding whether certification is appropriate.

5.1 *Methodology*

To assess whether the costs of the rule will lead to a significant economic impact on a substantial number of small entities, this analysis proceeds in four general steps.

(1) Select an appropriate indicator for measuring impacts;
(2) Estimate the incremental compliance costs of the final rule;
(3) Quantify the impacts and the number of entities impacted; and
(4) Evaluate the impacts.

Each of these steps is described below.

5.1.1 Selection of Impact Measure

The analysis evaluates impacts based on the ratio of annualized incremental cost as a percent of total revenue. This measure was selected after evaluating the following six candidate measures:

- *Incremental Cost.* This measure considers the increase in cost (present value) to a given entity resulting from the rule. The incremental cost is equivalent to the cost of obtaining a patent under the new rule minus the cost of obtaining a patent under the current rules. While intuitively simple, this measure does not address the significance of the cost relative to any characteristic (e.g., size) of the small entity that incurs the cost. Therefore, *incremental cost* is used in this analysis only as an intermediate result.

- *Annualized Incremental Cost.* This measure calculates what the annual incremental cost of the rule would be if the incremental cost (as described above) were financed and paid off in annual installments. This measure can be useful in situations where it is reasonable to allocate costs over a multi-year period. Spreading costs over time is generally appropriate for capital investments (e.g., equipment) that will contribute to income over an extended period. In the case of patents, for example, it is reasonable to allocate the cost of obtaining a patent over the 20-year life of the resulting patent, because the patent holder retains exclusive rights over the patent during that time. In fact, generally accepted accounting principles (GAAP) for amortizing patents require patents to be amortized over the life of the patent.[16] Nevertheless, this measure by itself does not address the significance of the cost relative to the entity that incurs it. Therefore, *annualized incremental cost* is used in this analysis only as an intermediate result.

- *Percent Increase in Costs.* This measure calculates the incremental cost as a percentage increase relative to the "baseline" costs, which are the costs applicable in the absence of the rule. The *percent increase in costs* can be useful, particularly when percentage increases are small. However, this measure does not address the significance of the cost relative to the entity that incurs the cost. For example, even if a rule leads to a 100 percent increase in costs, that increase might not be significant to an entity if the original cost is sufficiently small. In addition, estimating the "baseline" cost of preparing a patent application is difficult due to the difference between applications with respect to the complexity of the invention, the state of prior art, and the skills and experience of the applicant.

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[16] See, for example, S*tatement of Accounting Standards No. 142, Goodwill and Other Intangible Assets,* Financial Accounting Standards Board, June 2001.

- *Cost as a Percent of the Expected Value of the Patent.* This measure considers the incremental cost as a fraction of the expected value of the patent. In theory, this measure should be very useful in evaluating whether impacts are likely to be significant. In practice, however, this approach presents significant challenges. For example, it would not be possible to identify the expected value of individual patent applications, which would be ideal from a theoretical standpoint. Instead, it would be necessary to apply one or more average values and make related assumptions. This study evaluated the literature to find information on the value of patent applications and identified estimates ranging from $220,000 to $1.3 million. These finding do not appear sufficiently robust to support use of this measure for the present purposes (see Appendix B for further discussion). Finally, this measure would not recognize other types of value that patents and patent applications can provide to applicants (e.g., by providing enhanced competitive protection to existing business lines).

- *Incremental Cost as a Percent of Revenue*, and *Annualized Incremental Cost as a Percent of Revenue.* These measures consider cost as a percentage of an entity's total revenue – a common measure of an entity's size – and are common screening measures for evaluating whether costs are significant. All else equal, costs that are small relative to a firm's size are less significant than costs that are larger. Although other factors also influence whether a given cost is significant to an entity, such as the entity's profitability and its ability to "pass through" costs to its customers, these two ratios both are useful screening measures that are applicable to most types of entities.

- *Incremental Cost as a Percent of Profits.* Incremental cost relative to profits is often considered a useful measure of impacts because profit represents "net" revenue after all expenses have been paid. This measure raises some unique issues, however, including the "adequacy" of any given return on equity, the effect of tax incentives on small entities, and whether a cost should be considered "more significant" to firms that are managed poorly as opposed to firms that are managed more effectively. From a more mechanical perspective, profits data are relatively difficult to obtain, particularly when affected entities span numerous industries, as is the case with patent applicants.

This study focuses on *annualized incremental cost as a percent of revenue* for several reasons: (1) it considers costs on an annualized basis, which is consistent with the generally accepted recognition that a patent is an asset conveying a multiyear earning potential; (2) it evaluates impacts relative to revenue, which is a useful and relevant measure of the size of an entity; (3) it can be applied readily across many industries and entity types; (4) data availability typically is not an impediment to analysis; and (5) most people understand it without difficulty.

5.1.2 Estimation of Incremental Compliance Costs

The analysis estimates incremental costs resulting from the requirements of the final rule using the information and sources described in Section 4 and Appendix A. These sources include USPTO staff, AIPLA, and the USPTO fee schedules.

The resulting costs are summarized in Section 5.2. The incremental costs are annualized over a period of 20 years (to coincide with the life of the patent) using an interest rate of seven percent.

5.1.3 Quantify Impacts and Number of Entities Impacted

In the next step, the analysis quantifies the impacts of the final rule and the number of entities impacted at the identified thresholds (described in Section 5.1.4). Impacts are based on incremental costs calculated as described in Section 5.1.2. As noted previously, some costs (those associated with the claims requirements) are a function of the number of claims contained in an application. Therefore, the analysis appropriately models different incremental costs and impacts for filings having different numbers of included claims.[17] All estimates of the number or percentage of affected entities and the distribution of applications by number of claims are based on data from PALM for fiscal year 2006.

5.1.4 Evaluate the Rule's Economic Impacts

In the last step, the quantitative results are screened to determine whether the rule is likely to have a significant impact on a substantial number of small entities.

Significant Impact Criteria

To evaluate *significant impact*, the study considers the ratio of *Annualized Incremental Cost as a Percent of Revenue,* as described earlier. Impacts are evaluated relative to two screening thresholds:

- Entities at or above a threshold value of *three percent* are presumed to face significant impacts unless additional analysis of these entities indicates this will

[17] For applications affected only by the claims requirements, PALM provided data on the number of claims for each application. The analysis conservatively assumes that the filings (other than RCEs) affected by both the claims requirements and by the continued examination filing requirements are those non-initial applications shown by the PALM data as having the most claims. For RCEs, the analysis assumes the same distribution by number of claims as PALM shows for non-initial applications.

not be the case. Note that a three percent threshold is equivalent to determining whether an entity has annual revenue of at least 33.3 times the annualized incremental cost.

- Entities at or above a threshold value of *one percent* are presumed to face more moderate impacts that qualify as significant if collectively incurred by a *substantial number* of small entities, as discussed below. Note that a one percent threshold is equivalent to determining whether an entity has annual revenue of at least 100 times the annualized incremental cost.

Because the rule's incremental costs are relatively small, the analysis proceeds by considering how much annual revenue an affected entity – large or small –would have to earn in order to avoid these impacts. To the extent that these minimum levels are below the levels needed to run even the smallest business, then the analysis can conclude that the rule will not result in significant impacts. For purposes of analyzing this rulemaking, the smallest business is modeled as a sole proprietorship owned by a creative and/or technical individual who currently is capable of paying for or financing all necessary patent filing costs and maintenance fees (under current rules) associated with an application of a type that would be affected by the final rule. These filing and maintenance fees can vary by filing, but this study estimates that they range from $19,940 to $49,155 for filings that would be affected by the final rule. This study assumes that the minimum annual revenue that would support an individual's living expenses, as well as his/her patent filing and maintenance costs, is $75,000.[18] Therefore, the smallest business in the analysis would exceed the three percent threshold at annualized incremental costs of $2,250 or higher, and it would exceed the one percent threshold at annualized incremental costs of $750 or higher. Businesses that earn higher revenue would exceed these thresholds only at proportionately higher incremental costs.

Note that the above thresholds are intended to serve as screening-level indicators and may be overly sensitive for purposes of identifying economic impacts. For example, to the extent that affected entities may earn higher future revenue due to the commercialization of the patent, impacts based on current revenue levels will be overstated. Additional analysis would be needed to definitively determine whether entities exceeding this threshold are likely to incur significant impacts as a result of the rule.

Substantial Number Criteria

The key objective of this analysis is to determine whether the USPTO's final rule will result in a significant economic impact on a *substantial number* of small entities. The concept of a "substantial number" is necessarily relative, however. For purposes of analyzing this rulemaking, it is reasonable to consider it relative to the total number of

[18] Revenue of $75,000 is higher than the U.S. median income (which is slightly less than $50,000), but it seems reasonable in light of the creative/technical abilities of an individual seeking a patent, as well as his/her current ability to fund the development and processing of the patent application (under existing regulations) as well as the required maintenance fees.

small entities that apply for patents. The USPTO's PALM system indicates that, in FY 2006, there were a total of 111,178 patent filings submitted by entities claiming small-entity status.

Most of these small entities, however, will not incur costs under the final rule. Of those that are affected, some might face potentially significant impacts. This analysis assumes that a "substantial number" of small entities exists if the number if entities impacted at a given impact threshold (e.g., three percent of revenue) constitutes at least 20 percent of all small entities that apply for patents. The analysis considered developing a numerical threshold (e.g., 2,500) as another criterion for determining "substantial number," but did not do so for two reasons. First, it was clear that the final rule would not affect enough small entities to exceed any of the numbers that would have been considered. Second, given that the number of patent filings the USPTO receives increases by 7 to 8 percent per year when the economy is good, selection of a number that would be appropriate for this year's rulemaking likely would be inappropriate in the near future.

Assumptions and Uncertainties

The analysis relies on several data sources as documented throughout this report. In addition, two assumptions are worth noting.

First, due to data limitations, the analysis considered patent filings rather than applicants. To the extent that applicants might have more than one application in process at a time, this will tend to understate impacts. Although the assumption certainly does not hold true for many large firms, these firms have sufficient revenue to avoid significant impacts under the final rule. The assumption is much more reasonable, however, for the smallest firms, such as the sole proprietorship described above, which might face significant impacts under the rule. See additional discussion in Section 3.2.2.

Second, the analysis of the continued examination filing requirements assumes, as also discussed in Section 3.2.2, that most applicants who would have triggered the final rule's claims requirements based on the applications they submitted in FY 2006 will not trigger those requirements once the rule is promulgated. Instead, these applicants will choose to submit an initial application with fewer claims (to avoid having to prepare an ESD) and then will take advantage of the various steps in USPTO's patent application review process to add additional claims. The final rulemaking contains a description of how these applicants can prosecute their applications in this manner to avoid triggering the ESD requirement.

5.2 Results

The presentation of results is organized in three parts: (1) costs; (2) number of small entities affected by the rule; (3) magnitude of impacts; and (4) unquantified benefits.

5.2.1 Cost Results

This analysis estimates that incremental costs will range from $872 to $13,993.[19] Incurring the lowest of these incremental costs are those applicants affected only by the continued examination filing requirements. Applicants incurring incremental costs at the highest end of the range are those having the following three characteristics: (1) they are affected by the claims requirements and have the greatest number of claims (e.g., 350 total claims); (2) they did not choose to conduct a patent search in the baseline; and (3) they also are affected by the continued examination filing requirements. Most applicants will fall between the extremes, as they will be affected by the claims requirements but will have more typical (lower) numbers of claims. Exhibit 5-1 summarizes the cost results, which are discussed in greater detail in Section 4.

Exhibit 5-1
Summary of Incremental Costs and Annualized Incremental Costs

	Incremental Cost	Annualized Incremental Cost
Continued Examination Filing Requirements Only	$872	$82
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	$2,563-$10,136*	$242-$957*
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	$5,170-$13,121*	$488-$1,239*
Both, for applicants that already conduct a patent search in the baseline	$3,435-$11,007*	$324-$1,039*
Both, for applicants that do not conduct a patent search in the baseline	$6,042-$13,993*	$570-$1,321*

* Cost of preparing an Examination Support Document varies depending on the number of claims in the application. Range shown covers up to 50 independent claims or 350 total claims. The analysis does not assume a range of costs per application, but instead applies the specific cost appropriate to the number of claims in each application.

5.2.2 Number Affected by the Rule

Exhibit 5-2 summarizes the total number of filings that will incur any incremental cost due to the claims requirements, the continued examination filing requirements, or both. In each case, the number is less than two percent of filings. Looking at the rule as a whole, only approximately 3.69 percent of small entity filings are expected to incur any impacts under the final rule. Under the sensitivity analysis, in which all entities would be considered small entities, this percentage falls to approximately 3.46 percent.

[19] Current patent filing and maintenance costs for applications that would be affected by the final rule are estimated at between $19,940 and $49,155.

Exhibit 5-2
Number and Percent of Entity Filings Affected by Final Rule Requirements

	Small Entities		All Entities*	
	Number	Percent	Number	Percent
Continued Examination Filing Requirements Only	2,995	2.69% (of small entity filings)	10,402	2.55% (of all filings)
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	429	0.54% (of small entity initial applications)	1,550	0.54% (of all initial applications)
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	351	0.44% (of small entity initial applications)	1,268	0.44% (of all initial applications)
Both, for applicants that already conduct a patent search in the baseline	179	0.16% (of small entity filings)	508	0.12% (of all filings)
Both, for applicants that do not conduct a patent search in the baseline	146	0.13% (of small entity filings)	416	0.10% (of all filings)
Total for Final Rule**	4,100	3.69% (of small entity filings)	14,144	3.46% (of all filings)

*Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of *All Entities* as a sensitivity analysis.
** Percentages may not add due to rounding.

5.2.3 Magnitude of Impacts

Of the 3.69 percent of small entity filings that will incur any impacts under the final rule, very few – an estimated 54, or less than 0.05 percent – may exceed the minimal screening threshold of one percent, as shown in Exhibit 5-3. Moreover, no small entities applicants are expected to incur impacts at the more significant threshold of three percent, as shown in Exhibit 5-4. Under the sensitivity analysis, in which all entities would be considered small entities, an estimated 157 entities, or about 0.04 percent, may exceed the one percent threshold, and none would exceed the three percent threshold.

Exhibit 5-3
Number and Percent of Entity Filings Exceeding the 1 Percent Threshold for Annualized Incremental Cost as a Percent of Total Revenue

	Small Entities		All Entities*	
	Number	Percent	Number	Percent
Continued Examination Filing Requirements Only	0	0% (of all filings)	0	0% (of all filings)
Claims Requirements Only, for applicants that already conduct a patent search in the baseline	9	0.01% (of all initial applications)	24	0.01% (of all initial applications)
Claims Requirements Only, for applicants that do not conduct a patent search in the baseline	23	0.02% (of all initial applications)	76	0.02% (of all initial applications)
Both, for applicants that already conduct a patent search in the baseline	3	0.00% (of all filings)	7	0.00% (of all filings)
Both, for applicants that do not conduct a patent search in the baseline	19	0.02% (of all filings)	50	0.01% (of all filings)
Total for Final Rule **	54	0.05% (of all filings)	157	0.04% (of all filings)

*Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of *All Entities* as a sensitivity analysis.
**Totals may not add due to rounding.

Exhibit 5-4
Number and Percent of Entity Filings Exceeding the 3 Percent Threshold for Annualized Incremental Cost as a Percent of Total Revenue

	Small Entities		All Entities*	
	Number	Percent	Number	Percent
Continued Examination Filing Requirements	0	0%	0	0%
Claims Requirements, for applicants that already conduct a patent search in the baseline	0	0%	0	0%
Claims Requirements, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%
Both, for applicants that already conduct a patent search in the baseline	0	0%	0	0%
Both, for applicants that do not conduct a patent search in the baseline	0	0%	0	0%
Total for Final Rule**	0	0%	0	0%

*Some stakeholder have stated that the USPTO's PALM system understates the number of small entities submitting patent filings. Therefore, as described in Section 3.2, this study evaluates the bounding case of *All Entities* as a sensitivity analysis.

5.2.4 Unquantified Benefits

Partially offsetting the minor impacts of the rulemaking are certain unquantified benefits. The most significant benefit that will accrue to affected small entities seeking patents (and to larger patent applicants) will be the reduction in time required to complete the patent process. As described in Section 1.3, a reduction in processing time is one of the USPTO's key objectives for the rule. A second benefit that will accrue to small entities seeking patents (along with larger patent applicants) may be a reduction in patent fees relative to what those fees might rise to in the absence of the rule. By allowing patent examiners to more efficiently complete their examination of the most time-consuming patents, the rule should reduce the growth in the fee-recoverable cost base. Finally, PTO also expects the rule to contribute to higher-quality patents in many cases. This benefit accrues to society as a whole (including small entities) and might result in various efficiencies as well as a decrease in patent litigation.

5.3 Conclusion

This analysis estimates that the final rule will result in incremental costs that range from $872 to $13,993 per application (present value).[20] Based on the methodology and data described in this report, the resulting analysis indicates that no patent applicants will incur significant impacts (defined as annualized incremental costs in excess of three percent of revenue) due to the final rule. Although some applicants will exceed the lower screening threshold of one percent, the number of small entities in this category is estimated at only 54, or about 0.05 percent of all small entity applicants. Even using data for all applicants as a sensitivity analysis, only 157 small entity applicants fall into this category – 0.04 percent of all applicants. These figures do not meet the criterion for a "substantial number" of small entities. Therefore, this analysis concludes that USPTO's final rule will not result in significant economic impacts on a substantial number of small entities.

6. Duplicative, Overlapping, and Conflicting Rules

The USPTO is the sole U.S. government agency responsible for administering the patent system and granting patents. Therefore, no other federal, state, or local entity shares jurisdiction over the United States' patent system.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the Patent Cooperation Treaty (PCT)).

[20] Current patent filing and maintenance costs are estimated at between $19,940 and $49,155 for filings that would be affected by the final rule.

Nevertheless, the USPTO believes that there are no other duplicative or overlapping rules. Some public comments submitted in response to the notices of proposed rulemaking argued that the proposed rules conflict with provisions of the Paris Convention and/or the PCT. The final rulemaking explains why there are no conflicts with either the Paris Convention or the PCT.

7. Significant Alternatives Considered and Steps Taken to Minimize Impacts on Small Entities

In response to some of the comments received, USPTO considered a variety of alternatives to minimize the impacts on small entities. Section 7.1 describes the alternatives that were adopted as part of the final rule. Section 7.2 discusses other alternatives that were considered but not adopted.

7.1 Alternatives Adopted by USPTO

The USPTO implemented five alternatives in the final rule to minimize the impact on small entities. The first two alternatives relate to the claims requirements and the remaining three relate to the continued examination filing requirements. In the final rule, the USPTO changed the ESD requirement threshold from more than ten representative claims in an application (proposed rule) to more than five independent claims or more than 25 total claims in an application (final rule). This change reduces the number of small entities affected by the final rule.

In addition, under the final rule, the USPTO will not require small entities, as defined in 13 CFR 121.802, to include in their ESDs one of the elements that would have been required under the proposed claims rule. Specifically, the final rule will not require small entities (but will require large entities) to identify, for each reference cited, all the limitations of each of the claims (whether independent or dependent) that are disclosed by the references. The USPTO considers this element of the ESD to be the most challenging for patent applicants. As a result of this change, the costs associated with the final rule will be greatly reduced for small entities.

The third alternative adopted in the final rule changes the continued examination filing petition threshold from one continuation application, continuation-in-part application, or RCE (proposed rule) to two continuing applications (continuation or continuation-in-part applications), and no more than a single RCE in any one of the initial or two continuing applications (final rule). This change also reduces the number of small entities affected by the final rule.

As mentioned in Section 3.2.2, some comments requested that applicants continue to be permitted to file divisional applications serially (i.e., in the manner of continuations or continuation-in-parts), rather than in parallel (i.e., by submitting multiple related applications simultaneously), in order to spread out the associated cost burden over time.

In response, the final rule modifies the time period within which any divisional application must be filed. An applicant may currently and under the final rule file a divisional application to each non-elected invention if the USPTO issues a requirement that an application containing claims to multiple inventions be restricted to a single invention (a restriction requirement). The USPTO changed the divisional filing period requirement from during pendency of initial application (proposed rule) to during the pendency of the initial application or its two continuing applications (final rule). As a result, the costs incurred by affected entities will be spread over a longer time period, which will ease the cost burden on these entities.

The final alternative the USPTO implemented in the final rule changes the application of the continued examination filing provisions from any continued examination filing (any continuation, continuation-in-part, or RCE) filed on or after the effective date (proposed rule) to at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings (final rule).

7.2 Alternatives Considered But Not Adopted

The USPTO considered changing the proposed claims requirements to instead provide expedited examination to applications containing less than a set number of claims. The USPTO currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no more than twenty total claims) and who also provide an ESD. Therefore, the USPTO did not pursue this alternative in the final rule.

In addition, the USPTO considered another alternative to the proposed claims requirements. To minimize the impact on small entities, the USPTO considered not applying the ESD requirement to pending applications that have not yet been examined (the backfile). However, the final rule's ESD applicability threshold (i.e., applications having more than five independent claims or more than twenty-five total claims) means that most small entity applicants will not be impacted by the final rule or the decision to apply the final rule to the backfile. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backfile would mean that it would be calendar year 2010 before the USPTO would see any benefit from the change, and that the USPTO (and applicants) would be in a transition state until late calendar year 2011.

The USPTO also considered a change that affected both the claims and continued examination filing requirements. The alternative would have imposed additional fees for continued examination filings and/or a graduated excess claims fee schedule. Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the USPTO proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. The USPTO was unable to garner sufficient support from patent user groups for a patent fee structure including a graduated excess claims fees schedule or any additional fees for continued examination filings. Therefore, the USPTO did not adopt the alternative.

The final alternative the USPTO considered but did not adopt addressed the continued examination filing requirements. The change would have expanded the deferral of examination provisions to allow a longer deferral of examination. The USPTO currently has a provision (37 CFR 1.103(d)) under which an applicant may request deferral of examination for up to three years from the earliest filing date for which a benefit is claimed. The USPTO continues to study whether changes (e.g., an increased deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate, but notes that patent user groups have historically not favored increases in the deferral of examination. Therefore, the final rule does not contain this alternative.

Appendix A: Input Cost Estimates

Cost elements	Estimate	Description/Source
Patentability search - Simple	$1,000	AIPLA Report 2005, Table Q39o, 25th percentile, All Individuals
Patentability search - Complex	$2,500	AIPLA Report 2005, Table Q39o, 75th percentile, All Individuals
Applicant's time, prepare and attend client interview - Simple	$450	3 hours @ $150 (range from 3-21 hours)
Applicant's time, prepare and attend client interview - Complex	$2,400	16 hours @ $150 (range from 3-21 hours)
Attorney's fee for patent application - Simple	$7,000	AIPLA Report 2005, Table Q39e, 25th percentile, All Individuals
Attorney's fee for patent application - Complex	$15,000	AIPLA Report 2005, Table Q39c, 75th percentile, All Individuals
Application Filing Fee (Initial/Cont/CIP) (USPTO)	$500	USPTO FY2006 Fees
Excess independent claims fee (USPTO)**	$1,300	USPTO FY2006 Fees
Excess total claims fee (USPTO)**	$1,400	USPTO FY2006 Fees
Response to First Office Action - Simple	$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Response to First Office Action - Complex	$4,500	AIPLA Report 2005, Table Q39g, 75th percentile, All Individuals
Prepare CIP application, lawyer's fees	$3,500	USPTO staff estimate, September 12, 2006
Response to Final Office Action - Simple	$1,000	AIPLA Report 2005, Table Q39f, 25th percentile, All Individuals
Response to Final Office Action - Complex	$4,500	AIPLA Report 2005, Table Q39g, 75th percentile, All Individuals
Issue Fee (USPTO)	$700	USPTO FY2006 Fees
Lawyer fee to pay an Issue Fee - Simple	$350	AIPLA Report 2005, Table Q39l, 25th percentile, All Individuals
Lawyer fee to pay an issue Fee - Complex	$1,000	AIPLA Report 2005, Table Q39l, 75th percentile, All Individuals
First Maintenance Fee (USPTO)	$450	USPTO FY2006 Fees
Second Maintenance Fee (USPTO)	$1,150	USPTO FY2006 Fees
Third Maintenance Fee (USPTO)	$1,900	USPTO FY2006 Fees
Lawyer fee to pay Maintenance Fees - Simple	$150	AIPLA Report 2005, Table Q39n, 25th percentile, All Individuals
Lawyer fee to pay Maintenance Fees - Complex	$300	AIPLA Report 2005, Table Q39n, 75th percentile, All Individuals
RCE Fee (USPTO)	$395	USPTO FY2006 Fees
Petition Fee	$400	USPTO FY2006 Fees
Petition Preparation	$1,000	USPTO staff estimate, September 11, 2006

**Estimates of incremental costs are calculated based on the number of claims contained in each application. Estimated baseline costs, however, conservatively assume the application has 76 total claims and 16 independent claims, and therefore may understate the baseline costs.

Appendix B: Estimating the Value of Patent Applications

One way to measure the incremental cost of the proposed rule is to express the cost as a percentage of the expected value derived from the patent over its lifetime. Economists have been studying the expected lifetime market value of patents in order to measure the impact of technological innovation on the macro-economy. For reasons discussed below, however, estimates of patent value show significant variation among various studies and approaches.

One measure of the expected value is derived from estimating the total income from patented ideas. Eaton and Kortum (1995) estimated the value of all patented ideas in the U.S. to be about $197 billion in 1998. According to USPTO data, there were 84,272 patents granted in 1988 in the U.S. whereas the total number of patent applications in that year was 151,491. Thus, based on the income earned from patented ideas, the average value of a patent in 1988 was about $2.3 million per patent granted, and about $1.3 million per patent application.

Because of the hazard of imitation in some of the developing countries, economists estimating the worldwide value for patents (as opposed to in the domestic country only) find the average expected value to be significantly lower. For example, McCalman (2005) analyzed the worldwide value of patent applications filed by U.S. inventors in the same year as above, and estimated it to be about $163,700 per application in 1988.

Perhaps the most realistic measure of the market value of patents is provided by Hall, et al (2000). They matched USPTO's patent database to publicly traded firm-level data from Compustat to estimate the market value of patents. Using data from 1976 – 1992, they found the marginal shadow value of a patent to be $370,000. Drawing on USPTO data for this period, the ratio of patents granted to total applications was 59 percent. Therefore, the marginal shadow value of patent per application in this period was about $220,000.

This discussion illustrates the wide variation in the economics literature on lifetime patent values. One reason for such differences is whether the value of the patent is estimated for the U.S. only or for values accruing to patents around the world. Moreover, as Griliches, Hall, and Pakes (1987) point out, the distribution of the patent values is known to be extremely skewed with a few patents being very valuable, and many worth almost nothing. Any exercise in estimating the future value of patents or patent applications is, therefore, fraught with uncertainty and likely to produce extremely noisy measures.

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